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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,723	04/18/2001	Henry Daniell	1464-PCT-US-00	4031

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06/11/2002

Schnader Harrison Segal & Lewis
IP Department 36th Floor
1600 Market Street
Philadelphia, PA 19103

EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,723

Applicant(s)

DANIELL ET AL.

Examiner

Anne Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 6, 15-20 and 60, drawn to a chloroplast transformation vector encoding a Bt toxin and a chaperonin.

Group II, claim(s) 1, 4-6, 55 and 60, drawn to a chloroplast transformation vector encoding a Bt toxin and a cholesterol oxidase.

Group III, claim(s) 1, 4-6, 55 and 60, drawn to a chloroplast transformation vector encoding a Bt toxin and an alpha-amylase inhibitor.

Group IV, claim(s) 1, 4-6, 55 and 60, drawn to a chloroplast transformation vector encoding a Bt toxin and a protease inhibitor.

Group V, claim(s) 1, 4-6, 55 and 60, drawn to a chloroplast transformation vector encoding a Bt toxin and a cowpea trypsin inhibitor.

Group VI, claim(s) 1, 4-6, 55 and 60, drawn to a chloroplast transformation vector encoding a Bt toxin and a potato proteinase inhibitor II.

Group VII, claim(s) 1, 8, 10, 12 and 59, drawn to a chloroplast transformation vector encoding insulin.

Group VIII, claim(s) 1, 8, 10, 12 and 59, drawn to a chloroplast transformation vector encoding human albumin.

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Group IX, claim(s) 14, drawn to a method of combating insects via application of proteins.

Group X, claim(s) 1, 21-32, 37-42 and 60, drawn to a plant chloroplast transformation vector comprising MerA and MerB, a method of transforming a chloroplast with that vector to confer resistance to metal ions, and a plant so obtained.

Group XI, claim(s) 1, 23 and 37-50, drawn to a chloroplast transformation vector comprising MerA and MerB for transformation of a single-celled organism, a method of transformation, a method of phytoremediation, and transformed algae and cyanobacteria.

Group XII, claim(s) 1, 51-54 and 60, drawn to a chloroplast transformation vector encoding a monoclonal antibody.

Group XIII, claim(s) 1, 58 and 60, drawn to a chloroplast transformation vector encoding an amino acid biosynthetic pathway.

Group XIV, claim(s) 1, 58 and 60, drawn to a chloroplast transformation vector encoding an fatty acid biosynthetic pathway.

Group XV, claim(s) 1, 58 and 60, drawn to a chloroplast transformation vector encoding a carbohydrate biosynthetic pathway.

Group XVI, claim(s) 1, 58 and 60, drawn to a chloroplast transformation vector encoding a polymer biosynthetic pathway.

Group XVII, claim(s) 1, 58 and 60, drawn to a chloroplast transformation vector encoding a vitamin biosynthetic pathway.

Group XVIII, claim(s) 1, 58 and 60, drawn to a chloroplast transformation vector encoding an antibiotic biosynthetic pathway.

Group XIX, claim(s) 1, 58 and 60, drawn to a chloroplast transformation vector encoding a dye biosynthetic pathway.

The inventions listed as Groups I-XIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-VIII and X-XIX are unrelated to Group IX. The groups do not share a technical feature. Groups I-VIII and X-XIX are drawn to chloroplast transformation vectors, not required by Group IX. Group IX, on the other hand, is drawn to a method of combatting insects via topical application of proteins, which are not required by Groups I-VIII and X-XIX.

Groups I-VIII and X-XIX do not relate to a single general inventive concept because these inventions do not constitute an advance over the prior art. The technical feature shared by these inventions is a chloroplast transformation vector encoding multi-gene operon. This technical feature is disclosed by Maliga et al (US 5,877,402 A, 02 March, 1999, see Figure 22A and column 65, lines 19-39), who teach chloroplast transformation vectors where more than one gene is expressed from the same promoter. Thus, the shared technical feature is not special. These groups are deemed to lack unity of invention because they are not so linked to form a single general inventive concept.

The following sets of Groups are unrelated to one another: Groups I-VI, Groups VII-VIII, Groups X-XI and XIII-XIX, and Group XII. Groups I-VI are drawn to chloroplast transformation vectors encoding Bt toxins, Groups VII-VIII are drawn to chloroplast transformation vectors encoding a biopharmaceutical protein, Groups X-XI and XIII-XIX are drawn to chloroplast transformation vectors encoding biosynthetic pathways, and Group XII is

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drawn to chloroplast transformation vectors encoding a monoclonal antibody. Thus the Groups do not share a special technical feature.

The technical feature shared by Groups I-VI is a chloroplast transformation vector encoding a Bt toxin. This technical feature is disclosed by McBride et al (US 5,545,818 A, 13 August, 1996, see Figure 1, column 2, lines 24-60, and column 7, line 63, to column 8, line 5; cited in the PCT search report), who teach chloroplast transformation vectors that encode *Bacillus thuringiensis* crystal proteins. Thus, the shared technical feature is not special, and these groups are deemed to lack unity of invention because they are not so linked to form a single general inventive concept. The Groups are unrelated to each other because the vectors of each encode an additional protein, and this additional protein differs among each Group.

The technical feature shared by Groups VII and VIII is a chloroplast transformation vector encoding biopharmaceutical protein. This technical feature is not special because it is disclosed by Maliga et al (US 5,877,402 A, 02 March, 1999, see column 27, lines 14-32; cited in the PCT search report), who suggest the expression of insulin in plant chloroplasts. These Groups are thus deemed to lack unity of invention because they are not so linked to form a single general inventive concept. Group VII is unrelated to Group VIII because Group VII vectors encode insulin, while Group VIII vectors encode human albumin.

The technical feature shared by Groups X-XI and XIII-XIX is a chloroplast transformation vector encoding a biosynthetic pathway. This technical feature is not special because it is disclosed by Maliga et al (US 5,877,402 A, 02 March, 1999, see column 27, lines 53-59; cited in the PCT search report), who suggest the expression of biosynthetic pathway genes in plastids. As the Groups are drawn to different biosynthetic pathways, the Groups are unrelated.

The technical feature shared by Groups X-XI is organisms that express both MerA and MerB. This technical feature is not special because it is disclosed by Meagher et al (US 5,965,796 A 12 October, 1999, see column 14, lines 2-8 and column 12, lines 8-36; cited in the PCT search report), who suggest the expression both genes in the same plant and the use of those plants in bioremediation. Group X is unrelated to Group XI because Group X is drawn to expression of those genes in higher plants, while Group XI is drawn to expression of those genes in single-cell photosynthetic organisms.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.
May 7, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 160-1638

David T. Fox